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June 8, 2023

Via EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
Washington, DC 20549
Attention: Sasha Parikh, Kevin Vaughn, Jimmy McNamara, and Jason Drory

Re: MIRA Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted May 2, 2023
CIK No. 0001904286

Dear Ms. Parikh, Mr. Vaughn, Mr. McNamara, and Mr. Drory:

On behalf of MIRA Pharmaceuticals, Inc. (the "Company"), we are responding to the comments of the staff of the Division of Corporation Finance of the United States Securities and Exchange Commission set forth in your letter to Erez Aminov, the Company's Chief Executive Officer, dated May 29, 2023. Your comments are reproduced below in italicized bold text, followed by our responses on behalf of the Company. Please be advised that, concurrently herewith, the Company has submitted via EDGAR a Draft No. 2 of the above-referenced draft registration statement (such Draft No. 2 is referred to herein as the "Registration Statement").

Draft Registration Statement on Form S-1

Cover Page

1. ***Please disclose, if accurate, that the closing of this offering is contingent upon a Nasdaq Listing, or otherwise advise. Please ensure the disclosure is consistent with your underwriting agreement.***

Response: The Company has added a new sentence to the end of the second paragraph of the prospectus cover page expressly stating that the closing of the offering is contingent upon the successful listing of the Company's common stock on the Nasdaq Capital Market.

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2. ***We note that you have checked the Rule 415 box on your outside cover page, yet disclosures elsewhere indicate that this is a firm commitment, underwritten offering. Please advise or revise.***

Response: Please be advised that the Company checked the Rule 415 box on the registration statement cover page because the Registration Statement will register the issuance of the warrants issued to the underwriter and the shares issuable upon the exercise of such warrants. Page 10 of the Prospectus Summary has been revised (next to the caption "Representative's Warrants") to reflect that such warrants and the underlying shares are being registered.

Prospectus Summary, page 1

3. ***The disclosure in the summary should be a balanced presentation of your business. Please balance your prospectus summary by including disclosure regarding your limited operating history and your history of net losses.***

Response: In response to this comment, the Company moved the "RISK FACTOR SUMMARY" section from immediately following the Prospectus Summary into the Prospectus Summary. In addition, the Company inserted the following new sentence on the first page of the Prospectus Summary under the caption "Business Summary:" "We are an early-stage company with a limited operating history and had net losses of $7.1 million for the year ended December 31, 2022, and $2.2 million for year ended December 31, 2021, respectively."

4. ***We note your disclosure in reference to "studies" suggesting that MIRA1a may be capable of unmasking positive therapeutic effects not previously seen with THC. Please specify that these are preclinical studies, or otherwise advise.***

Response: In the last sentence of the paragraph under the caption "Business Summary," the Company inserted "preclinical" before "studies suggest." For the information of the Staff, the same change was made under the caption "Overview" in the Business section.

5. ***We note that disclosures here, and elsewhere in the prospectus, include statements or implications that your product candidates are safe and/or effective. Please revise these statements, as safety and efficacy determinations are in the exclusive purview of the FDA or other regulators. For example only, the following statements improperly state or imply that your product candidates are safe or effective:***

   - ***On page 2, your product candidate is "likely much more efficacious as a potential therapeutic for inflammatory, autoimmune, and neurodegenerative conditions."***
   - ***On page 2, that you found MIRA1a has "potent" anti-anxiety effects.***
   - ***On page 7, your belief that MIRA1a's expected "safety and toxicity profile" should provide an edge over existing medicines categories.***
   - ***On page 7, that you will be "using a safe, effective and FDA-approved treatment option."***

Response: In response to the Staff's comment, the Company has revised the disclosure in various places in the prospectus to state and reflect that product candidate safety and efficacy determinations are in the exclusive purview of the FDA and other regulators. The above-referenced language on page 2 of the originally submitted registration statement has been deleted. The above-referenced language on page 7 of the originally submitted registration statement has been qualified with language referencing the need for FDA approval (see page 7 of Registration Statement filed concurrently herewith) and a corresponding change has been made on page 53 of the Registration Statement concurrently filed herewith. Language has also been added to page 54 to explicitly state that safety and efficacy determinations are in the purview of the FDA. These changes are in addition to the previously included language and qualifications throughout the Registration Statement (including in the Risk Factors) referencing FDA approval requirements.

Pre-Clinical Developments and Studies, page 2

6. ***We note your disclosure of pre-clinical trials relating to your product candidate throughout this section. Please revise to clarify whether each trial was powered for statistical significance. In addition, if a trial was powered for statistical significance please provide p-values for the results of each trial.***

Response: The Company has added the following note to the "Completed Pre-Clinical Tests" table: "None of these studies were powered for statistical significance and no p-values are available."

7. ***At the top of page 3 you have a table of pre-clinical tests. Please revise your disclosure to clarify what "Group 1" and "Group 2" actually mean. In addition, we note that you include descriptions, including the results, of only some of your pre-clinical studies completed to date. If a pre-clinical study is material, please expand your disclosure in your Business section to provide a more fulsome discussion of the study design as well as the objective results.***

Response: Please be advised that the table entitled "Completed Tests" has been revised to eliminate the distinction between "Group 1" and "Group 2." The table has also been renamed "Completed Pre-Clinical Tests." In addition, pre-clinical studies that were listed in the table but that are not considered by management to be material (and for which fulsome descriptions were not previously provided) have been deleted from the list in the table, and the Company believes that the remaining studies in the list are subject to fulsome discussions in the Registration Statement.

Market Opportunity, page 6

8. ***We note your statistics on page 6 reference the global market for "medicines" as well as the United States market. We also note your disclosure on page 1 that your treatment is geared towards a particular demographic, namely, adult patients with anxiety and cognitive decline typically associated with early-stage dementia, as well as those with chronic pain. Please revise your disclosure or otherwise provide additional context on why the global and domestic statistics for all medicines is relevant given your current product candidate's apparent more narrow potential indications.***

Response: The language under "Market Opportunity" in the Prospectus Summary was revised to delete the statistics regarding the market for all medicines, both globally and in the U.S. We note that the disclosure under "Market Opportunity" in the Business section was correspondingly revised.

9. ***We note your reference on page 6 to an IQVIA Report that specifies statistics about the "global" CNS market, and that anxiety is worth between approximately $20 billion and $25 billion in annual sales. We also note your disclosure on page 7 that you currently have no plans to develop the MIRA1a compound for approval and commercialization outside of the United States, and that your license is for research and development activities as well as for commercial uses in the United States. Please tell us whether the global statistic is an accurate depiction of the market opportunity for your Company, particularly in light of the geographic scope of your current license, or otherwise advise.***

Response: The Company has revised this disclosure to include only the U.S. statistics, and corresponding changes were made under "Market Opportunity" in the Business section.

10. ***We note your disclosure that another "key market will be the traditional pain market, which the IQVIA Report estimates will be worth $42 billion in 2027 and grow between three and six percent during the forecast period." Please specify whether the estimates are for a domestic or global market, or otherwise advise.***

Response: The Company revised this disclosure to clarify that this estimate represents the U.S. market, and a corresponding change was made under "Market Opportunity" in the Business section.

Our Clinical Development Program, page 6

11. ***We note your disclosure on page 6, and elsewhere, that an overlapping (hybrid) Phase I and Phase II can be designed and allowed to proceed by the FDA, allowing you to "accelerate" the development of MIRA1a. Please provide balancing disclosure here, and elsewhere, that there is no guarantee the FDA will provide such approval and disclose whether you or your representatives have had any conversations with the FDA regarding an "overlapping" trial design. Finally, please revise this statement and any similar disclosure to remove any implication that you will be successful in developing your product candidate in a rapid or accelerated manner as such statements are speculative.***

Response: In response to the Staff's comment, the Company has revised the disclosure on page 6 and elsewhere, to provide balancing disclosures regarding the Company's plans to seek a hybrid Phase I and Phase II trial.

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12. ***We note your statement on page 6 that a Phase II trial for your first IND application "is planned to commence by the end of the fourth quarter of 2024" and a "Phase II trial will begin in the third quarter of 2026" for your second IND application. Given the lengthy timeline and uncertainty with regard to clinical development, please remove these statements as it appears to be premature and speculative given your stage of development.***

Response: These statements have been removed from the Registration Statement, both in the Prospectus Summary and also in the Business section.

Risk Factors, page 14

13. ***In light of your relationship with MyMD, please consider including a risk factor discussing risk resulting from any conflicts of interest or the appearance of conflicts of interest. In this regard, we note that certain of your executive officers are also senior management within MyMD. We also note your disclosures on page F-9 that "[t]he Company and MYMD have similar members of the Board, as well as officers from the respective companies."***

Response: The Company has added a new risk factor entitled "***Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with MyMD.***" See page 14 of the Registration Statement.

Use of Proceeds, page 39

14. ***We note your disclosure that you cannot specify with certainty the particular uses of the net proceeds that you will receive from this offering. Please revise your use of proceeds disclosure to provide more granularity regarding the first bullet point, namely how far in the development process you estimate that the proceeds will enable you to reach, including specific phases of clinical trials, if applicable. In this regard, we note your disclosure on page 22 that you have significant and increasing liquidity needs and may require additional funding.***

Response: In response to the Staff's comment, the Company has revised the Use of Proceeds to provide more specificity regarding the estimated uses and how far in the development process the proceeds will enable the Company to reach.

Capitalization, page 41

15. ***Please include debt in the capitalization table as a component to determining your total capitalization.***

Response: The capitalization table has been updated to include debt.

Management's Discussion and Analysis and Results of Operations
Results of Operations, page 44

16. ***For each of the periods presented, please quantify each factor identified for the increase/decrease in each of your expense line items. As part of your response, please address the following:***

    - ***Please revise your results of operations to provide a quantified breakdown of your research and development expense by nature or type of expense, and discuss each component, as applicable.***
    - ***Disclose how much of your $1.3 million in stock compensation expense was applicable to general and administrative expense and research and development expense.***

Response: In response to this comment, the Company added disclosure to the MD&A to include additional period-over-period comparison details, including quantifying the factors resulting in increases/decreases in expense items. Please see pages 43 and 44 of the Registration Statement. The Company also included disclosure on pages 43 and 44 distinguishing between general and administrative stock compensation expense and R&D stock compensation expense, and as stated in such disclosure, the Company did not have any G&A stock compensation expense in the periods presented.

Business
Market Opportunity, page 53

17. ***We note your graphic disclosure depicting the total addressable population on page 54. Please identify the referenced "published literature," and provide a more detailed discussion of the underlying assumptions used in your calculations.***

Response: Please be advised that the Company has deleted the graphic entitled "Summary of US Epidemiology" and the ensuing paragraph that referenced "published literature."

Our Market Advantage, page 54

18. ***We note your disclosures that "MIRA1a is the first cannabinoid that has demonstrated the ability to improve cognitive performance in pre-clinical studies." Please provide your basis for this statement. In addition, we note your disclosures on page 17 that conclusions based on your pre-clinical data may prove inaccurate, and are not necessarily predictive indicators of future results. Please provide balancing disclosure here, and elsewhere, regarding any conclusions and predictions you make based on preclinical studies.***

Response: Please be advised that the Company has deleted from the Registration Statement the sentence referenced in the first sentence of this Staff comment. The Company has added the following sentence to the discussion of the Company's pre-clinical studies on pages 2 and 49: "Our interpretation of results derived from pre-clinical data or our conclusions based on our pre-clinical data may prove inaccurate and are not necessarily predictive indicators of future results."

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19. ***We note your disclosure regarding the DEA's determination and your belief that MIRA1a has a distinct competitive advantage by being poised to move through the regulatory approval process at a "faster pace" than that of competing scheduled product candidates. Please remove this statement as the DEA's determination may not lead to a faster development or regulatory process, and also does not increase the likelihood that the product candidate will receive approval by the FDA. We further note your disclosure that your Company is positioned to enjoy market exclusivity in the United States "upon receiving regulatory approval." Please remove this statement as there is no guarantee that your product candidates will receive regulatory approval by the FDA or similar regulatory body.***

Response: In response to the Staff's comment, the Company has removed the statement regarding the DEA's determination and the Company's belief that MIRA1a has a distinct competitive advantage by being poised to move through the regulatory approval process at a "faster pace" than that of competing scheduled product candidates. Furthermore, in response to the Staff's Comment, the Company has removed the statement that it is positioned to enjoy market exclusivity in the United States "upon receiving regulatory approval."

Intellectual Property, page 56

20. ***We note your disclosure here that you own U.S. Patent 10,787,675 B2. Please disclose the expiration date of the patent.***

Response: In response to the Staff's comment, the Company has included the statutory expiration date of the U.S. Patent 10,787,675 B2 on Page 56.

Amended and Restated Limited License Agreement with MyMD Pharmaceuticals, page 76

21. ***We note your disclosure on page 7, and elsewhere, regarding the perpetual license you have with MyMD Pharmaceuticals, Inc. to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities as well as for commercial uses in the United States. We also note your disclosure on F-9 that you have entered into a non-exclusive, royalty-free license to use MYMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities relating to your planned pre-clinical and clinical studies. Please disclose, if accurate, that this is a non-exclusive license, or otherwise advise. In addition, please disclose the material terms of the agreement, including amounts paid to date, future potential payments, royalty provisions, and termination provisions or otherwise advise. We note the agreement appears to cover "commercial uses" in addition to research and development activities.***

Response: The subject disclosure has been revised to, among other things, state that the license from MyMD is non-exclusive and to include disclosure of other material terms that were not already included in the disclosure. As stated in the disclosure, the license is perpetual, royalty-free, and worldwide and does not involve any prior or future payments by us (other than consideration in the form of information sharing and licensing of certain improvements). The Company believes that the revised disclosure now includes all material terms and conditions of the license agreement.

22. ***We note your disclosure that you have the "right to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities as well as for commercial uses in the United States." Please clarify whether there are other third parties or other "synthetic intermediates" for which you could use to manufacture your product candidate, MIRA1a. To the extent MyMD is your sole supplier for your "synthetic intermediate" in the manufacture of MIRA1a, please disclose the risk relating your reliance on a sole-supplier and please disclose whether you believe alternate sources of the "synthetic intermediate" are available, or otherwise advise.***

Response: For the information of the Staff, MyMD is merely a licensor of the right to use MyMD's patent rights in Supera-CBD to make and use Supera-CBD as a synthetic intermediate, and MyMD does not actually supply the physical material. Accordingly, the Company has advised that MyMD is not and will not be a supplier for purposes of manufacturing MIRA1a. Furthermore, in response to the Staff's comment, the following sentence has been added in the subject paragraph on page 76 and also under "Intellectual Property" on page 56: "Although we believe that Supera-CBD is currently the best available synthetic intermediate for the manufacture of MIRA1a, we believe that other intermediates and/or processes could be used to manufacture MIRA1a."

Certain Relationships and Related Party Transactions
Line of Credit and Promissory Note with the Bay Shore Trust, page 76

23. Please tell us your accounting analysis with regards to the common stock purchase warrant issued to Bay Shore Trust citing supportive, authoritative accounting guidance, and revise to disclose your accounting for the warrant, providing quantification as applicable.

Response: The Company has advised that, upon issuance, the warrant met the criteria to be classified as equity based on an analysis under ASC 480, "Distinguishing Liabilities from Equity" (ASC 480) and will be measured at fair value, resulting in an initial fair value of approximately $3.5 million upon issuance of the warrant using Black-Scholes valuation techniques. Language has been added to the discussion of the warrant under "Certain Relationships and Related Party Transactions" to reflect this conclusion.

Note 5. Related party transactions, page F-7

24. Confirm, if true, that all related party transactions are separately quantified on the face of your statement of operations.

Response: The Company has advised that all related party transactions that have an impact on the statement of operations are separately quantified on the face of the statement of operations.

Notes to Financial Statements
Note 1. Description of business and summary of significant accounting policies
Research and Development Expenses, page F-7

25. You disclose on page 44 that legal costs included in your general and administrative expense line item include patent costs. However, you also disclose on page F-7 that your research and development expenses include patent-related costs. Please address the following:

- ***Revise to reconcile the apparent inconsistency between these disclosures.***
- ***Further, tell us how you considered the guidance of ASC 730-10-55-2(i), which outlines the type of patent costs that must be excluded from research and development expenses.***

Response: For the information of the Staff, there was no patent expense recorded in R&D, as patent expense is recorded in G&A. As such, the disclosure in the footnotes on F-7 regarding patent costs in R&D has been removed.

Note 8. Stockholders' Equity
Stock Based Compensation, page F-12

26. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

Response: The Company has taken note of the Staff's comment and the information that the Staff is requesting once an offering price range has been inserted, and the Company will make contact with the Staff to further discus how the response will be submitted.

General

27. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Response: The Company respectfully advises the Staff that the Company has not provided, nor has the Company authorized anyone to provide on its behalf, written communications to potential investors in reliance on Section 5(d) of the Securities Act of 1933, as amended. To the extent that such written communications are presented to potential investors by the Company or anyone authorized to do so on the Company's behalf in the future, the Company will supplementally provide such copies to the Staff (and coordinate with the Staff member how to submit such materials).

28. At first use, please define abbreviations throughout your draft registration statement. For example only, we note that "MTD/7D" and "DRF" on page 5, which do not appear to be defined.

Response: In response to the Staff's comment, the Company included definitions of various abbreviations throughout the registration statement, including definitions of "MTD/7D" and "DRF" on page 5.

29. Please ensure the writing is legible in the visual depictions throughout your draft registration statement. For example only, your visual at the top of page 2, contains legends and text on the y-axis that are not legible and with respect to the "Pain Reduction" Thermal Sensitivity visual on page 4, the writing above and below the yellow bar is not legible.

Response: In response to this comment, the Company has revised various of the visual depictions appearing in the Registration Statement and, as noted above, the Company has deleted the "Summary of US Epidemiology" graphic appearing on Page 55 of the originally submitted draft registration statement.

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Should you have any additional questions, please do not hesitate to contact the undersigned at 813.225.4122.

Best regards,

/s/ Curt P. Creely
Curt P. Creely